

### **REMARKS**

Upon entry of the following amendments, claims 1-14, 16-17, 19-20, 22-24, and 36-40 constitute the pending claims in the present application. Claims 25-33 are withdrawn. Claims 15, 18, 21 and 34-35 have been cancelled. Claims 1-14, 16-17, 19-20, 22-24, and 36-40 are rejected.

#### **Claim Amendments**

Applicants have amended claims 1, 10, 37 and 40 for clarity; support for these amendments can be found throughout the specification. Claims 11 and 16 have been amended to correct typographical errors. The present amendments do not add new matter.

#### **Summary of Telephonic Interview and Amendments**

Applicants appreciate the time and attention of Examiner Ryckman during the telephonic interview of October 22, 2008. During the interview the outstanding rejections of the pending claims were discussed.

In response to the 35 U.S.C. 112, first paragraph, rejection of claims 1-10, Applicants respectfully noted that Figure 72 of the specification depicts an embodiment in which the pusher tube and the implant form an interface along the substantially straight section of the proximal end of the shaft. The Examiner agreed that this figure satisfies the written description requirement. The Examiner noted that the "substantially straight section" referred to in claims 37 and 40 should be clarified to reference the substantially straight section of the proximal end of the shaft.

Regarding claim 1, the Examiner agreed that "interface" can be replaced with "operative connection" and thereby overcome the rejection based on U.S. 5,334,185 to Giesy et al. ("Giesy").

Issues raised in the Office Action will now be addressed below in the order they appear in the Office Action.

#### **Claim Rejections – 35 U.S.C. §112**

Claims 1-9 and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as having insufficient antecedent basis for the limitation "the implant." Applicants disagree. Applicants

assume that the phrase in question is "the implant" referenced in the phrase spanning the final and penultimate lines of claim 1. Applicants point to the phrase "an implant" referenced two lines previous to "the implant" and respectfully submit that there is sufficient antecedent basis for "the implant" as used.

Claims 37 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being unclear as to whether the "substantially straight section" refers to the shaft or the pusher tube. These claims have been amended to specify "the substantially straight section of the proximal end of the shaft."

Claims 1, 10, 25 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. On page 3 of the Office Action, the Office contends that the specification does not support the claim that the pusher tube is adapted to form an interface with the implant along the substantially straight section of the proximal end of the shaft. Applicants respectfully submit that Figure 72 depicts such an exemplary interface. Accordingly, Applicants request reconsideration and withdrawal of all rejections under 35 U.S.C. §112.

*Claim Rejections – 35 U.S.C. §102*

Claims 1-4, 7-9, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,334,185 ("Giesy"). Applicants traverse the rejection to the extent that it is maintained over the claims as currently amended.

As amended, claim 1 recites a delivery device for delivering an implant to an anatomical site in a body of a patient, the device comprising a handle, a shaft having proximal and distal ends and attached to the handle at the proximal end, the distal end having a curved section and the proximal end having a substantially straight section, a pusher tube slideably fitted over the shaft and extending from the handle distally along the substantially straight section of the proximal end of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push the implant into the anatomical site, wherein the pusher tube is adapted to form an operative connection with the implant along the substantially straight section of the proximal end of the shaft.

On page 4 of the Office Action, the Office asserts that the device of Giesy is "capable of being used with an implant that forms an interface with the straight section of the proximal end of the shaft." Nowhere in Giesy is it taught or suggested that an operative connection occur between the pusher tube and the implant along the substantially straight portion of the proximal end of the shaft. Indeed, the embodiments taught in Giesy describe only connections between sheath 22 and catheter 40 as occurring at the distal end of sheath 22, which position is distal to the curved section, and even further distal to the proximal end of the shaft. Nowhere does Giesy teach or suggest, among other things, an "operative connection" between a pusher tube and an implant along a substantially straight section of the proximal end of a shaft, and therefore this reference cannot anticipate or render obvious this claim or those dependent thereon. Accordingly, for at least these claims, Applicants request reconsideration and withdrawal of this rejection with regard to claim 1 and all of its dependent claims.

*Claim Rejections – 35 U.S.C. 103*

Claims 10-13, 17, 19, 20, 22-24 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,960,160 to Browning ("Browning") in view of U.S. 5,626,614 to Hart ("Hart") and in further view of Giesy. Applicants traverse the rejection to the extent that it is maintained over the claims as currently amended.

As amended, claim 10 recites a system for delivering an implant to an anatomical site in a body of a patient, the device having an implant for being delivered to an anatomical site in the body of a patient, and a delivery device including a handle, a shaft having proximal and distal ends and attached to the handle at the proximal end, wherein the distal end has a curved section and the proximal end has a substantially straight section, a pusher tube slideably fitted over the shaft and extending from the handle distally along the substantially straight section of the proximal end of the shaft, and a pushing mechanism operatively interconnected with the handle for actuating the pusher tube distally along the substantially straight section of the proximal end of the shaft to push the implant into the anatomical site wherein the pusher tube is adapted to form an operative connection with the implant along the substantially straight section of the proximal end of the shaft.

The Office correctly observes that Browning fails to teach or suggest the formation of an interface between a pusher tube and an implant along a substantially straight section of the proximal end of the shaft (See page 7 of the Office Action). But Applicants disagree with the Examiner's contention that Hart does (See page 7 of Office Action). Hart's Figure 11 depicts a surgical anchor bar 12 that abuts a push element 65, with push element 65 described as "a solid shaft" (Col 6, line 23). Hart's surgical anchor bar is to be inserted through body walls longitudinally to join such body walls together (Col 1, lines 11-13). As depicted in Figures 1 and 2 of Hart, this is done by mounting the anchor on an introducer 18 at the end 52 that is "distal" to, i.e., farthest away from, the handle 61. Applicants note that Hart's discussion of Figure 1 confuses "proximal" and "distal" and incorrectly refers to the end 52 as being "proximal" (see col 4, lines 38-40). However, Hart correctly refers to that end (i.e., the end farthest from the handle) as the "distal" end 50 when explaining close-up Figure 7 (see col 4, lines 54-55). Indeed, all of the embodiments shown by Hart position an anchor at the distal (or far) end of the shaft, not the proximal (or near) end. Moreover, mounting the anchor necessarily occurs at the distal end of the shaft; otherwise, the push element 65 would be unable to eject the relatively small anchor used by the Hart system. Applicants respectfully assert, therefore, that Hart fails to teach or suggest an operative connection between the anchor and the push element along a substantially straight section of the proximal end of the shaft.

As noted by Applicants above, Giesy also fails to teach or suggest this feature. Accordingly, Browning, Hart and Giesy, either alone or in combination, fail to teach all the features of claim 10, and therefore cannot be held to anticipate or render obvious that claim or its dependent claims. Applicants therefore respectfully request reconsideration and withdrawal of the rejections of claim 10 and its dependent claims.

Claims 5, 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesy and the combination of Browning, Hart and Giesy, and further as a matter of design choice.

On page 10 of the outstanding Office Action, the Office contends that Applicants failed to disclose that adding a second set of "recess, tongue and stop" for the pusher tube solves any stated purpose, and that such inclusion represents the mere duplication of the essential working parts of a

device. This feature is included in claims 5 (upon which claim 6 depends) and 14. Applicants respectfully refer to Paragraph 172 of the specification, which states "[t]he two-tongue configuration makes it even easier to operate the pusher assembly 30." Applicants respectfully submit that improving the ease of use of a device is very much a bona fide problem for which Applicants have provided a solution and, accordingly, request reconsideration and withdrawal of the rejections.

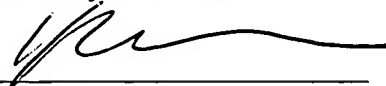
With respect to claim 16, the Examiner has provided no explanation or support for the rejection. Applicants respectfully remind the Examiner that the Federal Circuit recently articulated a standard whereby the PTO must establish a rational connection between the agency's fact-findings and its ultimate action. Dickinson v. Zurko, 119 S.Ct. 1816 (1999). In light of Applicants' arguments, and the presumption in favor of Applicants, it is respectfully asserted that the rejection is not supported by substantial evidence, and as such, fails to rise above the "arbitrary, capricious" standard applied under the "substantial evidence" test of Section 706(2)(E) of the Administrative Procedure Act. Applicants respectfully request withdrawal of the rejection.

### CONCLUSION

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P01-024 from which the undersigned is authorized to draw.

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Respectfully submitted,

By 

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